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09/475,963	12/30/1999	ROGER L. BUIS	BO999023-003	7122

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EXAMINER	
LUDWIG, MATTHEW J	

ART UNIT	PAPER NUMBER
2178	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/475,963	BUIS ET AL.	
	Examiner	Art Unit	
	MATTHEW J. LUDWIG	2178	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-16,24 and 26-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-16, 24, and 26-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the Request for Continued Examination received 6/18/08.

2. The Notice of Abandonment sent 5/16/08 has been withdrawn pursuant to applicant's previously filed RCE on 8/29/07 by facsimile which did not appear in PAIR.

3. Claims 10-16, 24, and 26-31, are pending in the case. Claims 10 and 24 are independent claims.

4. Claims 10-16, 24, and 26-31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Umen et al., USPN 6,854,086 filed (11/13/02) in view of Shoup USPN 7,076,502 filed (7,076,502).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. **Claims 10-16, 24, and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umen et al., USPN 6,854,086 filed (11/13/02) in view of Shoup et al., USPN 7,076,502 filed (4/12/2004).**

In reference to independent claim 10, Umen teaches:

Section headings may be included in the document templates for identifying the various sections of each document. At each location within the document template where a data object is

to be retrieved from the clinical study data base, there is a control code identifying which object is to be retrieved (compare to "***associating an identifier with each record in a data stream at a first computer, the identifier indicating a type of information included within a data record***"). See column 17, lines 20-35.

Each of the document templates specifies the type and order of data objects that are to be retrieved from the clinical study database in order to produce a standard drug document in accordance with FDA, EU, Company, or other predetermined document formats. Table 1 lists representative study details that may be specified within representative standard types of documents (compare to "***associating each identifier with a format region, each format region defining an area on a document page***"). See column 10, lines 35-55.

When the user selects Document Generation from the main menu, the DMUI provides a series of study selection menus which allow the user to specify whether the desired document pertains to a single study or whether the desired document integrates data from more than one study, and to select the study of interest (compare to "***specifying parameters for each format region, where the parameters include formatting instructions relating to the presentation of the data records in a document at a second computer***"). See column 17, lines 33-67. The reference fails to explicitly state the parameter are directly related to a format region; however, the parameters selected by the user for specifying dates of studies suggests the placement of data into specific regions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the parameters and predefined templates for the transmitting of document layouts effecting specific document regions for production of a standard drug document in accordance with FDA, EU, Company, or other predetermined document formats.

When the DMUI has completed generating the document, the document can be provided to the word processor for any desired editing or refinement by the user (compare to "***formatting each data record within the corresponding format region according to the parameters specified at the second computer***"). See column 19, lines 25-45.

The Umen reference discloses templates used for specifying the arrangement of information within a particular type of document to be generated. The generated drug data is presented to a user in a specific format based upon a reviewer of the data. A developer may also wish to produce internal company reports, which may also present the same drug data in another customized format. Umen fails to explicitly state layout identifiers controlling placement of each data within each format region. However, Shoup teaches a record management system for generating a multi-dimensional view for different measures. A set of records is retrieved in response to a set of queries. More specifically, a layout engine designates specific data into specific regions of the document based upon formatting parameters. See column 16, lines 30-67 and column 17, lines 45-67. Once the formatting information is gathered, the record management system proceeds with the generation of a layout mapping. The layout engine builds the layout mapping in the layout mapping storage unit by utilizing the retrieved formatting information and the record structure foundation formed by the query map and master table index. It would have been obvious to one of ordinary skill in the art, having the teachings of Umen and Shoup before him at the time the invention was made, to modify the data formatting methods of Umen and added the layout engine of Shoup, because it would have given the user an added multi-dimensional view of information based upon formatting instructions.

The examiner would like to make note of independent claim 10 which recites 'each layout identifier controls placement of each data record within each format region'. As presently claimed, the language of the claim fails to preclude the examiner from interpreting the format region as a page. The claim does not state multiple format regions and is interpreted as one format regions or a page. The reference discloses information regarding control codes. Control codes identify specific objects to be retrieved and placed within distinct document templates. More specifically, the control codes are associated with the section headings included in a document template. If one is to look at document templates which include different format regions, section headings which identify various sections of each document, and control codes that control the data input into the document template, than one could understand the suggestion of an association between the control codes and the placement of data according to different codes. The newly formed limitation which states ***'fixed data to be included in a format region Each time a particular layout identifier is encountered***' is taught by the reference to Umen. Each of the document templates specifies the type and order of data objects that are to be retrieved from the clinical study database in order to produce a standard drug document in accordance with FDA, EU, Company, or other predetermined document formats. See column 17, lines 33-67 and column 19, lines 25-45.

In reference to dependent claim 11, Umen teaches:

When the DMUI has completed generating the document, the user can provide the document to the word processor for any desired editing or refinement. Additionally, the user may

then instruct the word processor to operate the printer for printing the generated document. See column 19, lines 35-45.

In reference to dependent claim 12 and 13, Umen teaches:

The Umen reference discloses templates used for specifying the arrangement of information within a particular type of document to be generated. The generated drug data is presented to a user in a specific format based upon a reviewer of the data. A developer may also wish to produce internal company reports which may also present the same drug data in another customized format. Umen fails to explicitly state layout identifiers controlling placement of each data within each format region. However, Shoup teaches a record management system for generating a multi-dimensional view for different measures. A set of records is retrieved in response to a set of queries. More specifically, a layout engine designates specific data into specific regions of the document based upon formatting parameters. Once the formatting information is gathered, the record management system proceeds with the generation of a layout mapping. The layout engine builds the layout mapping in the layout mapping storage unit by utilizing the retrieved formatting information and the record structure foundation formed by the query map and master table index. It would have been obvious to one of ordinary skill in the art, having the teachings of Umen and Shoup before him at the time the invention was made, to modify the data formatting methods of Umen and added the layout engine of Shoup, because it would have given the user an added multi-dimensional view of information based upon formatting instructions.

In reference to dependent claim 14-16, Umen teaches:

The document generation option of the main menu provides access to procedures for generating drug documents on the basis of pre-defined document templates and information contained within the clinical study database. Each of the document templates specifies the type and order of data objects that are to be retrieved from the clinical study database in order to produce a standard drug document. The reference fails to explicitly state each data record formatted within a format region of a first type repeated at the beginning of each page of the document. However, Shoup teaches a record management system for generating a multi-dimensional view for different measures. A set of records is retrieved in response to a set of queries. More specifically, a layout engine designates specific data into specific regions of the document based upon formatting parameters. Once the formatting information is gathered, the record management system proceeds with the generation of a layout mapping. The layout engine builds the layout mapping in the layout mapping storage unit by utilizing the retrieved formatting information and the record structure foundation formed by the query map and master table index. It would have been obvious to one of ordinary skill in the art, having the teachings of Umen and Shoup before him at the time the invention was made, to modify the data formatting methods of Umen and added the layout engine of Shoup, because it would have given the user an added multi-dimensional view of information based upon formatting instructions.

In reference to claims 24, and 26-31, the claims reflect the computer program instructions used for performing the methods as claimed in 10-16. In further view of the following, the claims are rejected under similar rationale.

Response to Arguments

7. Applicant's arguments with respect to claims 10-16, 24, and 26-31, have been considered, but are not persuasive.

The examiner would like to make note of independent claim 10 which recites 'each layout identifier controls placement of each data record within each format region'. As presently claimed, the language of the claim fails to preclude the examiner from interpreting the format region as a page. The claim does not state multiple format regions and is interpreted as one format regions or a page. The reference discloses information regarding control codes. Control codes identify specific objects to be retrieved and placed within distinct document templates. More specifically, the control codes are associated with the section headings included in a document template. If one is to look at document templates which include different format regions, section headings which identify various sections of each document, and control codes that control the data input into the document template, than one could understand the suggestion of an association between the control codes and the placement of data according to different codes. The newly formed limitation which states 'fixed data to be included in a format region Each time a particular layout identifier is encountered' is taught by the reference to Umen. Each of the document templates specifies the type and order of data objects that are to be retrieved from the clinical study database in order to produce a standard drug document in accordance with FDA, EU, Company, or other predetermined document formats.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Ludwig whose telephone number is 571-272-4127. The examiner can normally be reached on 9:00am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Hong can be reached on 571-272-4124. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen S. Hong/
Supervisory Patent Examiner, Art Unit 2178

ML